Schedule-Y permits clinical trials for molecules discovered outside India and such clinical trials can be carried out by "multi-national pharmaceutical companies, local companies, global Clinical Research Organizations (CROs) and local CROs. For drugs discovered outside India, the concomitant clinical trails are permitted for Phase-II. Phase-III and Phase-IV and repeat Phase-I clinical trials are permitted to be conducted in India. The requirements specified under GCP and Schedule-Y have enough provisions to take care of ethical issues and safety of the subjects undergoing clinical trials.

The applicant for global clinical trials has to furnish detailed information with respect to objective of the study, participating countries, number of patients to be enrolled, approvals of institutional Review Board (Ethical Committee), details of serious adverse reactions reported, an affidavit indicating that the studies are not discontinued, safety data, animal pharmacology data, data of the previous Phases of clinical trials etc. for examination. After examination on the matter, an NOC is granted for conducting a trial with specific instructions about requirements of approval of ethical committee before starting of trial.

As per the requirements of Schedule-Y any unexpected serious adverse event (SAE) occurring during a clinical trial should be communicated by the investigator to the sponsor within 24 hours, by the investigator to the ethics committee within 7 working days, and by the Sponsor to the Licensing Authority and to the other Investigator(s) participating in the study within 14 calendar days.

During the past 3 years, 389 proposals for global Clinical trials were received. No serious adverse events have been reported so far.

Keeping in view the increase in the global and local clinical trials, the Government has made a provision in the Bill for amendment of the Drugs and Cosmetics Act, 1940, for creation of Central Drug Authority of India, recently introduced in the Rajya Sabha, by incorporating a clause for punishment for violation in conducting of clinical trials which provides for an imprisonment of 5 years and a fine up to Rs. 10 lakhs for first offence and for subsequent offences imprisonment of 10 years and a fine of Rs. 20 lakhs. The Bill has now been referred to the Parliamentary Standing Committee.

New pharma policy

*342. SHRI RAVI SHANKAR PRASAD:
DR. M.A.M. RAMASWAMY:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether Government are aware of the fact that large scale pharma companies are behind delay in announcing the New Pharma Policy by the Government; and

(b) if so, what are the steps taken by Government to expedite finalization of Pharma Policy in public interest in order to bring down the prices of medicines and to stop unintended profits by pharma companies on medicines?

THE MINISTER OF CHEMICALS AND FERTILIZERS (SHRI RAM VILAS PASWAN): (a) and (b) Draft National Pharmaceutical Policy was considered by the Cabinet at its meeting held on 11.1.2007. The Cabinet has referred the Policy to Group of Ministers (GOM). The First meeting of the GOM was held on 10.4.2007. After discussions it was decided to hold further meetings.

Rail projects in Tamil Nadu

*343. DR. V. MAITREYAN: Will the Minister of RAILWAYS be pleased to state:

(a) the ongoing and completed rail projects in Tamil Nadu during the last three years and the dates of commencement of the projects completed so far;

(b) the pending projects of the ongoing schemes undertaken in Tamil Nadu, the total cost of the projects and the amount allocated to each of the project during the last three years, project-wise and year-wise; and

(c) the exact time by which these projects are likely to be completed and the steps taken by Government to expedite these pending projects?

THE MINISTER OF RAILWAYS (SHRI LALU PRASAD): (a) to (c) Year-wise and project-wise details of outlay provided to the ongoing and completed projects falling fully/partly in the State of Tamil Nadu during the last 3 years alongwith year inclusion in the Budget, anticipated cost of the projects, sections completed during last three years and till date and targets wherever fixed are given in the enclosed Statement (*See* below). In order to expedite these projects a number of initiatives have been taken for generating additional resources through Public Private Partnership, Cost sharing by State Governments, Funding from Ministry of Defence and through Ministry of Finance for National Projects. Funds have also been allocated through internal resources generation to expedite completion. The ongoing projects would be completed in the coming years as per the availability of resources.